GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3222
ANSWERED ON:12.03.2003
PERMISSION FOR NEW DRUGS
BALIRAM;P.R. KHUTE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether in certain cases the permission for new drugs has been granted within a short period of one month`s time whereas in most of the other cases the time taken is much more;

(b) if so, the details thereof;

(c) the details of the applications received for the new drug permissions, alongwith the date of receipt and the date of approval by DCGI during 2002;

(d) the details of pending applications including the names of the drugs and companies;

(e) the number of drugs whose clinical trials is being done alongwith the names of the drugs, companies and the centres approved for the trial; and

(f) the manner in which the authenticity of such trials is monitored?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE(SHRI A. RAJA)

(a) & (b) No Sir. Evaluation of new drug applications is a complex process and time taken varies according to the nature of the application.

(c) In the year 2002, about 1017 applications of various categories of new drugs were received. A list of new drugs approved during the year 2002 alongwith date is annexed.

(d) & (e)Information is being collected and will be laid on the table of the House.

(f) Clinical trials are required to be conducted by qualified clinical investigators as per Good Clinical Practice (GCP)guidelines and after due approval by Institutional Ethics Committee. The Ethics Committeeare also required to follow `Ethical Guidelines For Biomedical Research on Human Subjects` published by ICMR and monitor the trial.

ANNEXURE

NEW DRUGS APPROVED FROM 1-1-2002 TO 31-12-2002.

S. NO.	NAME OF DRUG	APPLICATION DATE	APPROVAL DATE
1.	Meropenan Inj.	07-08-2001	08-01-2002
2.	Dimatoprost - Opth.	28-03-2001	08-01-2002
3.	Fosinopril Sod.	23-03-2001	10-01-2002
4.	Zaleplon	30-05-2001	17-01-2002
5.	Montelukast Sodium	07-11-2000	13-02-2002
6.	DtaP Vaccine	16-07-1997	01-02-2002
7	Thymogen	15-12-1997	12-02-2002

8.	Mifepristone	25-06-1996	13-02-2002
9.	Mecobalamin Inj.	03-01-2002	14-02-2002
10.	Dexrazoxen	27-09-2000	26-02-2002
11.	Bicalutamide	21-05-2001	07-03-2002
12.	Apraclonidene	27-01-1998	15-03-2002
13.	Mizolastine	20-07-2001	15-03-2002
14.	Miltefosine (C/T initiated on 12-11-1996)	27-02-2002	15-03-2002
15.	Loteprednol	31-07-2001	15-03-2002
16.	Ziprasidone	09-04-2001	15-03-2002
17.	Tranexamic Acid	24-04-2001	16-03-2002
18.	Abcavir	11-06-2001	22-03-2002
19.	Nadifloxacin	07-12-1998	28-03-2002
20.	Famcyclovir	25-11-2000	11-04-2002
21.	Tamsulosin	20-08-1998	15-04-2002
22.	Nateglinide	05-07-2000	01-05-2002
23.	Larcanidipine	10-01-2002	07-05-2002
24.	Quetiapine	07-11-2001	31-05-2002
25.	Itopride	27-09-1999	09-05-2002
26.	Alprostradil	10-12-1997	09-05-2002
27.	Isotretinoin	16-01-2000	21-06-2002
28.	Nebivolol	19-04-2000	12-07-2002
29.	Pygenum A. Extract	20-06-1995	30-07-2002
30.	Serolimus	09-07-1999	15-07-2002
31.	Drotrecogin alpha	27-03-2002	23-07-2002
32.	Valdecoxib	09-04-2002	01-08-2002
33.	Thalidomide	23-04-2002	12-08-2002
34.	(S)-Amlodipine	26-06-2001	16-08-2002.
35.	Cabergoline	20-08-2001	05-09-2002
36.	Butorphenol	13-03-2000	11-09-2002
37.	Gemtuzumab	02-11-2000	12-09-2002
38.	Quinapril	18-07-2001	19-09-2002
39.	Valacyclovir	16-09-1998	25-09-2002
40.	Fosphenytoin	05-11-2001	01-10-2002
41.	Ceftiofur	11-02-2002	08-10-2002
42.	Metexalon	23-11-2001	08-10-2002
43.	Acamprosate	16-07-2001	30-10-2002
44.	Cefepime	31-07-2001	30-10-2002
45.	Tegaserod Maleate	21-3-2002	01-11-2002
46.	Aztreonam	01-5-2001	01-11-2002
47.	Parecoxib	14-6-2002	01-11-2002
48.	Balasalazide disodium	27-6-2001	12-11-2002
49.	Cefetamet Pivoxil	20-11-2000	14-11-2002
50.	Telmisartan	11-2-2002	25-11-2002
51.	Levocetrizine	15-3-2002	12-12-2002
52.	Poractant	01-5-2002	24-12-2002
53.	Reboxetine	01-11-2001	31-12-2002